Job Description

Regulatory Affairs Specialist Nordics

September 2018

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The company

Company:	Abcur AB
Role:	Regulatory Affairs Specialist Nordics
Reporting to:	Senior Specialist - Regulatory Affairs - Nordic

Abcur AB *is a part of Concordia International, a diverse healthcare company with products available in over 100 countries and an annual turnover of approximately 1 billion USD. Today, there are 380 employees worldwide and 13 in our Helsingborg office.*

We focus on the development, registration and marketing of a wide range of niche prescription and non-prescription products within the Nordic markets for a number of vital therapeutic indications including addiction, intensive care, pain management, ophthalmology, endocrinology and anaesthesia.

We supply three product ranges: Abcur products, Amdipharm products and Mercury Pharma products, please see Appendix 1.

Our products are manufactured by certified European producers and are made according to European law and in agreement with GMP (Good Manufacturing Practice), as well as in accordance with European environmental requirements. To reduce global transport all Abcur products are manufactured within the European Union.

The Association of the Pharmaceutical Industry (LIF) is an association for the research based pharmaceutical industry. As a LIF member we comply with the ethical rules for pharmaceutical companies.

For more information about Abcur AB and Concordia international, please see
www.abcur.se
www.concordiarxinternational.com

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The role as Regulatory Affairs Specialist Nordics

The main purpose of the role as Regulatory Affairs Specialist Nordics:

- Primarily act as the main point of contact with Nordics Regulatory Authorities and internal/ external stakeholders of Concordia International (Nordics) Office (Regulatory partners, translators, Quality, Supply Chain, Medical/PV, Commercial) for Nordics portfolio of Concordia and work cross-functionally
- As part of the wider Global Regulatory Affairs team, having overall responsibility for post-approval/life-cycle Regulatory activities in the Nordic markets (Sweden, Norway, Finland, Denmark, Iceland), for the Company Nordics portfolio (> 100 Marketing Authorisations (MAs))
- Review of Applications to ensure correctness regarding submission category/ grouping or any other local requirements based upon the Nordics authorities.

The role requires an organized, structured, accurate, independent and pro-active way of working. You must have strong analytical and project management skills combined with a communicative ability and being detail oriented. The position puts high demands on being able to act independently but also effectively collaborating internally as well as externally.

As the company is relatively small, you must have a positive can do, will do attitude, not be afraid to roll up your sleeves and wanting to progress the department forward, by doing the job to the best of your ability. You will report to the Senior Specialist - Regulatory Affairs - Nordic. The position is located at the head office in Helsingborg.

Key responsibilities

General

- Proactively communicate any relevant legislative changes within Global Regulatory Affairs and to other internal stakeholder
- Liaise with other stakeholders within Concordia International (Nordics) and within the wider Concordia International team to manage expectations cross-functionally, as well as keeping an oversight of various Regulatory life-cycle management activities
- Provide regulatory support for any marketing authorisation applications
- Ensure an appropriate communication with Competent Authorities to facilitate productive dialogue regarding submissions and any issue-management
- Provide Regulatory support for any Competent Authority inspections

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Post-approval

- Maintain a strong and co-operative relationship with the Competent Authorities in the Nordic markets and any Regulatory partners
- Work closely with the wider Global Regulatory Team to manage post-approval activities for Company MAs within the Nordic markets in a timely and compliant manner with appropriate strategic oversight and direction.
- Manage communication with regional CMOs regarding Regulatory activities, as appropriate
- Manage Change Control/Deviation activities regarding Company MA Regulatory activities
- Manage activities to meet external and internal compliance requirements for Company MAs
- Manage regulatory activities for out of stock situations in the Nordics for Company MAs
- Regulatory Team member in the Nordic office cross-functional meetings
- Participate in tender submissions by interpretation of local requirements and management of any supporting Regulatory documentation
- Administration of local product information systems (Nordics-wide) e.g., FASS, DKMAnet, and MPA-linked product database
- Proof-read and approve relevant Nordics promotional material
- Perform/administrate applicable local translations
- Local approval of artworks
- Approval of local regulatory costs, as applicable
- Ensure that all Regulatory data/documentation is accurately recorded, held and communicated with relevant internal and external stakeholders

Key accountabilities

- Excellence in the Company product portfolio in the Nordic markets
- Ensure review of applications (more from the perspective of right categorisation, grouping and any local requirements) prepared by the Regulatory Team and providing comments in a timely manner facilitating submission to regulatory authorities.
- Ensure an oversight of labelling compliance levels for the Nordic products - Nordics specific Blue box/QRD change and any other labelling related guidance, work closely with Regulatory team for revisions/ submissions as and when needed
- Ensure all Regulatory submissions, correspondence and approvals are accurately communicated (internally and externally) recorded and filed to ensure compliance
- Ensure correct handling of changes/deviations in the Company Quality Management System
- Excellent working knowledge of product/current issues in Nordic markets and local Regulatory requirements
- Deliver solutions to Nordic issues in collaboration with partners and internal stakeholders
- Precise alignment with Regulatory (and other) partners in respect of on-going and required activities
- Effectively manage and build working relationships with Competent Authorities (where applicable), based on transparency, trust and clear communication

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- Excellent cross-functional teamwork with local colleagues and colleagues in the wider Concordia business to ensure full compliance and no preventable Regulatory cause for lack of product in the market
- Accountable for ensuring that the Regulatory document management system has the most current and accurate approved information for products in the Nordics portfolio

Qualifications, Knowledge & Experience

- Bachelor's degree in Pharmacy or Life Science. Post graduate qualification in a relevant scientific discipline is desirable.
- At least 5 years of Regulatory affairs experience across Nordics market within the Pharmaceutical Industry
- Very good understanding of EU regulations, should be able to provide professional advice on regulatory matters pertaining to Nordics
- Experience of working with external suppliers and partners
- Experience in electronic Regulatory document management systems
- Relevant European Regulatory Affairs training
- Excellent knowledge of Swedish and English, reading and writing. Knowledge of other Nordic languages are useful.

Competencies & Skills

- Builds wide and effective networks of contacts inside and outside the organisation, relates well to people at all levels
- Ability to work collaboratively in a cross-functional/cultural environment and with internal parties & external partners and agencies. Relates well well to people at all levels.
- Applies specialist and detailed technical expertise
- Excellent analytical skills
- Customer-focused, achieves project goals, sets high standards for quality and quantity, and works in a systematic way. Approaches work with a sense of urgency
- Sets strategies, plans and implements projects. Plans activities and projects well in advance and takes account of possible changing circumstances, excellent attention to detail.
- Works productively in a high pressure environment, maintains a positive outlook at work. Persists- does not give up despite barriers and obstacles. Role model of desirable behaviours and ways of working.
- Innovative solution finding
- Influencing and negotiating

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Opportunities with the role

You will join a growing organization that puts people in focus. You will have the opportunity to work in a global organization with colleagues in the UK, Ireland and India.

Together with the General Manager Nordic and the rest of the Concordia team you will be part of the important expansion of the Nordic region where regulatory affairs play an important role in keeping and expanding the product portfolio.

Contact

For inquires and more information about the position, please contact:
Catharina Herbertsson or Eva Runnerström, Recruitment consultants at PeakSearch.
catharina.herbertsson@peaksearch.se, +46 (0)706 152 772
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Application

Apply for the position at www.peaksearch.se

PeakSearch *is a recruitment consultant company specialized in recruiting Executives, Managers and Specialists in the Nordics. We have developed a top-quality recruitment model to attract, select and deliver the optimal match to our candidates and clients. Our talent network is huge and all our consultants have a long experience from the industry. PeakSearch headquarters is situated in central Stockholm, with affiliates in Lund, Uppsala, and selected partners in the Nordic countries.*

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Appendix 1 – Products

Abcur Products

Abcur (Nordic division of Concordia International) focus on the development, registration and marketing of a wide range of niche prescription and non-prescription products within the Nordic markets for a number of vital therapeutic indications including addiction, intensive care, pain management, ophthalmology, endocrinology and anaesthesia.

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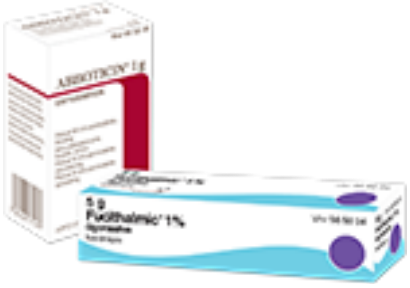
ABCUR

AMDIPHARM



MERCURY PHARMA

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